K000815

JUN - 8 2000

Premarket Notification 510(k) Summary
As required by section 807.92
AS/3™ Anesthesia Monitor with S-ANE99(A), L-ARK99(A) software

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

Datex-Ohmeda, Inc.
3 Highwood Drive
Tewksbury, MA 01876
Tel: 978-640-0460
Fax: 978-640-0469

NAME OF CONTACT:

Mr. Joel Kent
FDA Official Correspondent

DATE:

June 7, 2000

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

AS/3™ Anesthesia Monitor with S-ANE99(A), L-ARK99(A) software

COMMON NAME:

Patient monitor

CLASSIFICATION NAME:

The following Class III classifications appear applicable:
Arrhythmia detector and alarm (per 21 CFR 870.1025)
Monitor, ST segment with Alarm (per 21 CFR 870.1025)

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The Datex-Ohmeda AS/3™ Anesthesia Monitor with S-ANE99(A), L-ARK99(A) software is substantially equivalent to the AS/3™ Anesthesia Monitor (K933285), AS/3™ Record Keeper (K923172) and Marquette ElectronicsTram® Patient Monitor (K900540).

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DEVICE DESCRIPTION as required by 807.92(a)(4)

The AS/3™ Anesthesia Monitor with S-ANE99(A)/L-ARK99(A) is typically furnished with a module that measures ECG, invasive and non-invasive blood pressures, pulse oximetry and temperature. Modules are placed in the AS/3™ monitor frame and are automatically recognized by the monitor. The patient cables are connected to the module plug in jacks and then monitoring can begin.

The AS/3™ Anesthesia Monitor with S-ANE99(A)/L-ARK99(A) can display measurements in the form of numeric values, traces and trends. Audible and visual alarms are used to indicate patient status. The priority profile of an alarm depends on the parameter.

The AS/3™ Anesthesia Monitor with S-ANE99(A)/L-ARK99(A) is operated by a keyboard. Typically pressing a key results in a pop up menu appearing on the screen. Selections can then be made easily from the menu using a unique ergonomically designed pointing device on the keyboard called a ComWheel™.

When appropriate modules (which have separate 510(k) clearances) are inserted the software S-ANE99(A)/L-ARK99(A) performs some module related tasks like arrhythmia analysis, ST-values calculation, heart rate calculation, impedance and respiration rate calculation, energy expenditure calculation, EEG spectrum analysis and evoked potential response averaging. All the module communication is also handled in the main software.

L-ARK99(A) includes the same software as S-ANE99(A) and also the option of creating patient care documentation. The trend information is automatically transferred to the anesthetic record, and the related events and medication can be easily entered with the same user interface as the monitor itself.

There are various optional types of keyboards, some are like standard keyboards and another is a hand-held Remote controller (REMCO) which is still directly connected to the AS/3™ Anesthesia Monitor via a long cord but provides more flexibility in controlling the monitor while the doctor or nurse is handling other patient care needs. Using the recordkeeper software, patient related care events are documented using the keyboard. To facilitate quick access to menus, a bar code reader is also available.

The AS/3™ Anesthesia Monitor can be in a stand-alone or networked configuration. If networked, measurements are sent to the network for central station or monitor-to-monitor viewing. Trends as well as the patient care documentation can be sent via a network to a central computer for archiving.

INTENDED USE as required by 807.92(a)(5)

The AS/3™ Anesthesia Monitor with S-ANE99(A)/L-ARK99(A) is intended for multiparameter patient monitoring with optional patient care documentation.

The AS/3™ Anesthesia Monitor with S-ANE99(A)/L-ARK99(A) is indicated for monitoring of hemodynamic (including arrhythmia and ST-segment analysis), respiratory, ventilatory, gastrointestinal/regional perfusion and neurophysiological status of all hospital patients. The AS/3™ Anesthesia Monitor with L-ARK99(A) is also indicated for documenting patient care related information. The AS/3™ Anesthesia Monitor with S-ANE99(A)/L-ARK99(A) is indicated for use by qualified medical personnel only.

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SUMMARY OF TECHNOLOGICAL CHARACTERITICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The Datex-Ohmeda AS/3™ Anesthesia Monitor with S-ANE99(A), L-ARK99(A) software is substantially equivalent to the AS/3™ Anesthesia Monitor (K933285), AS/3™ Record Keeper (K923172) and Marquette ElectronicsTram® Patient Monitor (K900540).

The Datex-Ohmeda AS/3™ Anesthesia Monitor with S-ANE99(A), L-ARK99(A) is indicated for monitoring of hemodynamic (including arrhythmia and ST-segment analysis), respiratory, ventilatory, gastrointestinal/regional perfusion and neurophysiological status of all hospital patients.
The AS/3™ Anesthesia Monitor with L-ARK99(A) is also indicated for documenting patient care related information.

There are four software options available for the AS/3™ Anesthesia Monitor: S-ANE99 and S-ANE99A (collectively referred to as S-ANE99(A)), and L-ARK99 and L-ARK99A (collectively referred to as L-ARK99(A)). (Note: S- refers to software and L-to software license. There is no physical difference in the products) Only one software can be used at any given time in the monitor. The software is preloaded in the factory.

The new device with different software options, AS/3™ Anesthesia Monitor with S-ANE99(A), L-ARK99(A), is compared to predicates as outlined below

The basic model of the monitor is the AS/3™ Anesthesia Monitor with S-ANE99 , which is a new revision of the predicate device, AS/3™ Anesthesia Monitor (K933285).

When the basic model is equipped with the additional functionality of documenting patient care related information the monitor is called AS/3™ Anesthesia Monitor with L-ARK99. The AS/3™ Anesthesia Monitor with L-ARK99 is a new revision of the predicates, AS/3™ Anesthesia Monitor (K933285) and AS/3™ Record Keeper (K923172).

Both the AS/3™ Anesthesia Monitor with S-ANE99 and AS/3™ Anesthesia Monitor with L-ARK99 may also be equipped with extended bedside arrhythmia analysis capability and in this case the monitor is called AS/3™ Anesthesia Monitor with S-ANE99A or AS/3™ Anesthesia Monitor with L-ARK99A respectively. The arrhythmia analysis functionality of the AS/3™ Anesthesia Monitor with S-ANE99A and AS/3™ Anesthesia Monitor with L-ARK99A are substantially equivalent to the functionality of the predicate device Marquette Tram® Patient Monitor (K900540).

In summary, the AS/3™ Anesthesia Monitor with L-ARK99, L-ARK99A software is identical to in terms of compared to monitoring possibilities as with S-ANE99, S-ANE99A. The L-ARK99, L-ARK99A software simply extend the capability to document patient care related information.

The AS/3™ Anesthesia Monitor with S-ANE99(A), L-ARK99(A) software is thus substantially equivalent to the AS/3™ Anesthesia Monitor (K933285) and AS/3™ Record Keeper (K923172).

The AS/3™ Anesthesia Monitor with S-ANE99(A), L-ARK99(A) is a modular multiparameter patient monitor providing connections to measurement modules. The general construction of the AS/3™ Anesthesia Monitor with S-ANE99(A), L-ARK99(A) and intended use are the same as for the predicate AS/3™ Anesthesia Monitor (K933285) and AS/3 Record Keeper (K923172). However, indications for use are slightly different from the predicates due to the introduction of new measurement modules (parameters). These new measurement modules are the subject of their own separate 510(k) premarket notifications.

The Marquette Electronics Tram® Patient Monitor (K900540) is also a modular multiparameter monitor with basic construction similar to the AS/3™ Anesthesia Monitor with S-ANE99(A), L-ARK99(A). The indications for use for the predicate Marquette Electronics Tram® Patient Monitor (K900540) is for use as a multiparameter patient monitor throughout the hospital. Parameters that can be measured with the predicate Marquette Electronics Tram® Patient Monitor (K900540) include a sub-set of parameters measured by the AS/3™ Patient Monitor with S-ANE99(A), L-ARK99(A) Software.

The predicate device Marquette Electronics Tram® Patient Monitor (K900540) includes optional arrhythmia analysis software similar to the AS/3™ Anesthesia Monitor with S-ANE99(A), L-ARK99(A).

The Datex-Ohmeda AS/3™ Anesthesia Monitor with S-ANE99(A), L-ARK99(A) software is as safe and as effective as the predicates AS/3™ Anesthesia Monitor (K933285), AS/3™ Record Keeper (K923172) and Marquette Electronics Tram® Patient Monitor (K900540). It is evident that the main features and indications for use of the AS/3™ Anesthesia Monitor with S-ANE99(A), L-ARK99(A) software is substantially equivalent to the combination of the AS/3™ Anesthesia Monitor (K933285), AS/3™ Anesthesia Record Keeper (K923172) and Marquette Electronics Tram® Patient Monitor (K900540).

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

The DATEX-OHMEDA AS/3™ Anesthesia Monitor with S-ANE99(A), L-ARK99(A) software is in compliance with safety standards and is therefore safe and effective for the intended use. The device has been thoroughly tested including electrical safety, electromagnetic compatibility, mechanical and environmental tolerance, software validation and verification of specifications. Verification of compliance to the following mandatory and voluntary standards have been made:

- IEC 60601-1:1988+ Amdt.:1:1991 + Amdt. 2:1995
- EN 60601-1: 1990 + A1:1993+A2:1995+A13:1996
- CAN/CSA-C22.2 No.601.1-M90 +S1:1994+Amdt. 2:1998
- IEC 60601-2-27:1994/EN 60601-2-27:1994
- IEC 60601-2-30:1995/EN 60601-2-30:1995
- IEC 60601-2-34:1994/EN 60601-2-34:1994
- IEC 60601-2-40:1998
- IEC 60601-1-2(1993)/EN 60601-1-2
- IEC 60601-1-4: 1996/EN 60601-1-4
- ISO 9918:1993/EN 864:1996
- ISO 9919:1992/EN865:1997
- ISO 7767:1997/EN12598:1999
- ISO 11196 (1995) + Corr. 1:1997/EN ISO11196(1997)
- IEC 60601-2-10:1987/HD 395.2.10:1989
- IEC 60601-2-26:1994/EN60601-2-26
- UL 2601-1:1994
- ANSI/AAMI ES-1 (1993)
- ANSI/AAMI EC57:1998
- FDA 21 CFR 898.12

Conclusion:
The summary above shows that there are no new questions of safety and effectiveness for the DATEX-OHMEDA AS/3™ Anesthesia Monitor with S-ANE99(A), L-ARK99(A) software as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 8 2000

Mr. Joel C. Kent
Manager, Quality and Regulatory Affairs
DATEX OHMEDA, INC.
3 Highwood Drive
Tewksbury, MA 01876

Re: K000815
Trade Name: AS/3 Anesthesia Monitor with S-ANE99(A)/L-ARK99(A)
Regulatory Class: III (three)
Product Code: 74 MHX
Dated: March 10, 2000
Received: March 13, 2000

Dear Mr. Kent:

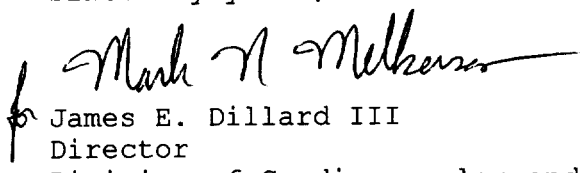
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: AS/3™ Anesthesia Monitor with S-ANE99(A)/L-ARK99(A)

The AS/3™ Anesthesia Monitor with S-ANE99(A)/L-ARK99(A) is indicated for monitoring of hemodynamic (including arrhythmia and ST-segment analysis), respiratory, ventilatory, gastrointestinal/regional perfusion and neurophysiological status of all hospital patients.

The AS/3™ Anesthesia Monitor with L-ARK99(A) is also indicated for documenting patient care related information.

The AS/3™ Anesthesia Monitor with S-ANE99(A)/L-ARK99(A) is indicated for use by qualified medical personnel only.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ **OR** **Over-The-Counter Use** _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

for _____
(Division Sign-Off)
Division of Respiratory,
and Neurological Devices
510(k) Number K000815